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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,749	12/23/1999	JENNIFER L. HILLMAN	PF-0519-1DIV	7908

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n No.

09/471,749

Applicant(s)

HILLMAN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21,22,27-30 and 41-45 is/are pending in the application.  
4a) Of the above claim(s) 24,25,29,30,41 and 42 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 21,22,27,28 and 43-45 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 10 February 2004.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Claims 21, 22, 24, 25, 27-30 and 41-45 are pending.

Claims 24, 25, 29, 30, 41 and 42, drawn to non-elected inventions are withdrawn from examination.

Claims 21, 22, 27, 28 and 43-45 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicants request a rejoinder of claims 24, 25, 29, 30, 41 and 42 with the examined claims 21, 22, 27, 28 and 43-45. At this point in prosecution this request will not be granted. The product, which is currently examined is not allowable. When the product is designated as such the instant request will be granted. See *In re Ochiai* and *In re Brouwer*.

4. The declaration under 37 CFR 1.132 filed October 29, 2003 is insufficient to overcome the rejection of claims 21, 27, 28 and 43-45 based upon 35 USC § 112, first paragraph (enablement and written description) as set forth in the last Office action because: of the reasons set forth below.

***Maintained Rejections***

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 21, 27, 28 and 43-45 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained.

Applicants direct the Examiner's attention to case law regarding the legal requirement of 35 USC § 112, as well as the Furness declaration. Applicants point out in the specification definitions of claim language germane to the instant rejection. Applicants also aver that the Examiner has misapplied the enablement guidelines. In conclusion Applicants assert that have provided enablement commensurate with the scope of the claimed invention and "...have enabled one reasonable skilled in the art to ...make and use the claimed invention without undue experimentation". The declaration has been carefully reviewed and the points of view have been considered, but found unpersuasive.

One of ordinary skill in the art could assay molecules in an effort to define and classify the said molecule. However, it would require undue experimentation to practice the invention given the limited evidence found in the specification. The specification is silent as to which amino acids could be deleted or substituted to render polypeptides consistent with the activity and function of the wild-type molecules. Furthermore, the specification does not disclose what portions of SEQ ID NO: 3 or 5 could be used as fragments capable of eliciting an immune response and retaining biological activity.

The Furness declaration submitted by Applicants with as Paper number 26, received October 29, 2003 suggests that the implementation of SEQ ID NO: 3 and SEQ ID NO: 5 as tools in conducting protein expression analyses, 2-D PAGE mapping or western analysis techniques in furtherance of the development of drugs and analyses of the efficacy and toxicity of said drugs. However, the declaration does not establish enablement of mutant and variant molecules that may differ in structure and function from the wild-type sequences. Notwithstanding, SEQ ID NO: 3 and 5 have not been clearly characterized. The specification exemplifies no examples of the effective use of the sequences consisting of SEQ ID NO:3 or SEQ ID NO:5, nor fragments and variants of these polypeptides as a pharmacological agent, applicability to diagnostic assays or drug discovery. The scope of the claims must bear a reasonable correlation with the scope of enablement. In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to using the myriad of contiguous amino acid residues and variants encompassed in the scope of the claims, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

6. The rejection of claims 21, 22, 27, 28 and 43-45 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants present arguments drawing attention to the Office's guidelines regarding 35 USC § 112. Applicants also argue that variant and naturally-occurring sequences have been adequately described in the specification and given the detailed description of the chemical and structural features of SEQ ID NO: 3 and SEQ ID NO: 5 a skilled artisan would understand that the inventor would be possession of the claimed invention at the time of filing. These arguments have been considered but found unpersuasive.

The genus of polypeptides denoted as naturally –occurring having at least 90% sequence identity to the sequences of SEQ ID NO: 3 and 5, biologically-active and immunogenic comprises undefined sequences encompasses a variety of subgenera with widely varying attributes. The specification discloses only the alleged structural features of two species, the polypeptide sequences of SEQ ID NO:3 and 5. The written description guidelines mandate that a representative number of species belonging to a genus demonstrate function and structure commensurate in scope be disclosed and be in possession of Applicant. It is essential that there is a functional and structural correlation which defines the species. The claims and the specification provide insufficient evidence setting forth the critical features of the claimed invention and its relation to its critical function. The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed. Therefore, one of skill in the art would not be convinced that Applicants had possession of more than SEQ ID NO: 3 or 5 at the time of filing.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
10 February 2004